# STATE OF NEW JERSEY DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS

## ADMINISTRATIVE ORDER AND NOTICE OF RULE ADOPTION PURSUANT TO P.L. 2020, c. 18

#### IMMUNIZATION ADMINISTRATION BY PHARMACY TECHNICIANS

#### DCA Administrative Order No. 2021-02

Administrative Order and Temporary Rule Adoption by Paul R. Rodríguez, Director, Division of Consumer Affairs

Date: January 5, 2021

Authority: P.L. 2020, c. 18

Effective Date: January 5, 2021

Expiration Date: Concurrent with the end of the state of emergency or the public health emergency declared pursuant to Executive Order No. 103 (2020) (EO 103), whichever is later.

\* \* \*

WHEREAS, on March 9, 2020, through EO 103, the facts and circumstances of which are adopted by reference herein, Governor Murphy declared both a public health emergency and a state of emergency throughout the State due to the public health hazard posed by coronavirus disease 2019 (COVID-19); and

WHEREAS, the public health emergency declared in EO 103 has been extended through Executive Order Nos. 119, 138, 151, 162, 171, 180, 186, 191, 200 and 210 (2020) issued on April 7, May 6, June 4, July 2, August 1, August 27, September 25, October 24, November 22, and December 21, 2020, respectively, and continues to exist today; and

WHEREAS, on April 14, 2020, Governor Murphy signed into law P.L. 2020, c. 18, which permits the Director to issue administrative orders to suspend temporarily any provision of Title 45 of the Revised Statutes or suspend or modify temporarily any rule adopted pursuant to such authority, or to adopt temporarily any rule relating to the practice of any profession licensed or certified by a board in the Division of Consumer Affairs ("Division"), upon concurrence by the Attorney General, after determining that such order is necessary to promote the public welfare and further such other purposes of the state of emergency or public health emergency declared in EO 103; and

WHEREAS, the Pharmacy Practice Act, N.J.S.A. 45:14-40 to -82, provides for the registration of pharmacy technicians, and N.J.S.A. 45:14-80 sets forth the tasks pharmacy technicians may perform under the immediate supervision of a pharmacist; and

WHEREAS, N.J.S.A. 45:14-63 and N.J.A.C. 13:39-4.21 permit pharmacists to apply to the Board of Pharmacy to receive pre-approval to administer vaccines and related emergency medications to patients after demonstrating that they have satisfied the training and experience required for that approval; and

WHEREAS, on August 24, 2020, the Secretary of the United States Department of Health and Human Services ("HHS") issued a Third Amendment to the Declaration issued under the Public Readiness and Emergency Preparedness Act ("PREP Act") for medical countermeasures against COVID-19, which was first issued on March 10, 2020 ("Third Amendment"), determining that licensed pharmacists should be authorized to order and administer vaccines including vaccines against childhood diseases and influenza, to children ages three and over, subject to certain requirements, including that the vaccines be ordered and administered according to the Advisory Committee on Immunization Practices ("ACIP") standard immunization schedule for administration to children ages three and over; and

WHEREAS, on September 3, 2020, the Assistant Secretary for Health at HHS issued "Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act," ("September Guidance") which found that pharmacists are positioned to increase access to vaccinations because of their location and convenience, as well as their relationships with their patients, medical providers and hospitals, and therefore, as an "Authority Having Jurisdiction" under the PREP Act, the September Guidance authorized Statelicensed pharmacists to order and administer to persons three years of age and older, COVID-19 vaccines that have been authorized or licensed by the United States Food and Drug Administration ("FDA"); and

WHEREAS, on October 20, 2020, the Assistant Secretary for Health at HHS issued an additional Guidance (the "October Guidance") finding that pharmacy technicians who are licensed or registered by the state in which they are working and acting under the supervision of a qualified pharmacist, should be permitted to administer FDA-authorized or FDA-approved COVID-19 vaccines to individuals ages three and over and to administer FDA-authorized or FDA-licensed childhood vaccines to children ages three through eighteen according to ACIP's standard immunization schedule, subject to certain specific conditions; and

WHEREAS, the October Guidance specified that in order for pharmacy technicians to be qualified to administer vaccines and be considered "covered persons" under the PREP Act, they must satisfy the following requirements:

- the vaccination must be ordered by the supervising qualifying pharmacist;
- the supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians;

- the vaccines must be FDA-authorized or FDA-licensed;
- in the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);
- in the case of a childhood vaccine, the vaccination must be ordered and administered according to the ACIP standard immunization schedule for administration to children ages three and older;
- The qualified pharmacy technician must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- The qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation.
- The qualified pharmacy technician must complete a minimum of two hours of ACPE approved, immunization-related continuing pharmacy education during the relevant State licensing period(s).
- the supervising pharmacist must comply with recordkeeping and reporting requirements of
  the jurisdiction in which he or she administers vaccines, to include informing the patient's
  primary care provider when available, submitting required immunization information to
  the State immunization information system (vaccine registry), and with requirements with
  respect to reporting adverse events;
- the supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician; and
- the pharmacy technician must inform childhood vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refers patients as appropriate; and
- the supervising qualified pharmacist must comply with any applicable requirements (or conditions of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s); and

WHEREAS, on December 3, 2020, the Secretary of HHS issued a Fourth Amendment to the Declaration under the PREP Act, that, among other things, incorporated the terms of the September Guidance and October Guidance to clarify that pharmacists and pharmacy technicians are "Qualified Persons" for purposes of the PREP Act when they administer certain vaccines, including vaccines against COVID-19, and clarified certain training requirements for pharmacists; and

WHEREAS, expansion of the scope of practice of pharmacy technicians who have received the required education and training to administer vaccines against COVID-19 to patients ages three and over, and childhood vaccines to children ages three through seventeen, when supervised by a qualified pharmacist, will enable pharmacists to use their clinical training where required, and expand the workforce available to safely administer all vaccines to patients; and

WHEREAS, the State Board of Pharmacy, has established by regulation, at N.J.A.C. 13:39-4.21, the education and training qualifications for pharmacists to administer vaccines and related emergency medications, limited to diphenhydramine and epinephrine, which requirements are equivalent to or exceed the education and training established as threshold requirements for pharmacists to qualify to administer vaccines set forth in the Fourth Amendment, and therefore be qualified to supervise pharmacy technicians administering vaccines; and

WHEREAS, N.J.A.C. 8:57-3.16 requires that every health care provider that administers vaccines to children less than seven years of age must register as an NJIIS site and authorized user and report the administration of a vaccine to a child less than seven years of age within 30 days of administration; and

WHEREAS, on December 4, 2020, through EO 207, Governor Murphy required that all individuals, regardless of age, shall be enrolled in the NJIIS prior to or concurrent with receipt of a COVID-19 vaccination in New Jersey, if the individual is not already participating in the NJIIS at the time of vaccine administration, to enable appropriate tracking of COVID-19 vaccines; and

WHEREAS, to effectuate the purpose of tracking vaccines as set forth in EO 207, it is anticipated that all COVID-19 immunizations administered to patients of all ages will be required to be reported to the NJIIS, all pharmacists that intend to administer COVID-19 vaccines must ensure that the pharmacy practice site at which administration occurs is registered with NJIIS and that authorized users of the system and those who will administer vaccines are also registered, as well as comply with the reporting requirements as set forth by the New Jersey Department of Health and the CDC, as well as any other requirements imposed by federal law and/or the COVID-19 vaccination provider agreement; and

WHEREAS, pursuant to N.J.S.A. 45:14-63(c), the obligation to report any immunizations which are required to be reported to the NJIIS for inclusion in a patient's registry is placed upon the supervising pharmacist only, even if the vaccine is administered by a pharmacy technician; and

WHEREAS, authorizing qualified pharmacy technicians to administer vaccines to children in no way substitutes for or replaces the need for regular well visits with a patient's pediatrician or primary care practitioner, and, therefore pharmacy technicians be required to inform patients, and their parents or guardians, that there remains a need for regular well visits, and to independently inform their patients' primary care providers of all vaccines administered; and

WHEREAS, in consideration of the Third Amendment, the September Guidance, the October Guidance, and the Fourth Amendment, the Division finds good cause, following consultation with the Department of Health, for the duration of the state of emergency, to expand

the pool of individuals authorized to administer childhood vaccinations and vaccines against COVID-19 to include supervised qualified pharmacy technicians, and that such expansion may be helpful in maintaining childhood immunities and mitigating the risk to children and their communities of outbreaks of vaccine-preventable diseases as well as aid New Jersey's efforts to control and mitigate the effects of the pandemic;

**NOW, THEREFORE**, I, Paul R. Rodríguez, Director of the Division of Consumer Affairs, by virtue of the authority vested in me by the statutes of this State, and upon concurrence by the Attorney General, determine that this ORDER is necessary to promote the public welfare and further such other purposes for which the state of emergency and public health emergency was declared, and hereby ORDER as follows:

### 1. General requirements applicable to both COVID-19 vaccinations and childhood vaccinations:

- a. Pharmacy technicians shall be authorized to administer childhood vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, to children three through seventeen years of age, and COVID-19 vaccines to patients ages three and older, subject to the following conditions:
  - i. The pharmacy technician must hold a current, valid registration as a pharmacy technician in New Jersey; individuals with pending applications for registration as a pharmacy technician may not administer vaccines until registered and preapproved consistent with paragraph 1(b); and
  - ii. The pharmacy technician must obtain pre-approval from the Board to administer vaccines by completing an application and demonstrating compliance with the education and training requirements set forth in the October Guidance, including a practical training program that is approved by the ACPE, and that must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines and a current certificate in cardiopulmonary resuscitation.
- b. A registered pharmacy technician shall act only under the direct supervision of the supervising pharmacist, who shall be a licensed pharmacist pre-approved by the Board to administer vaccines and related emergency medications, pursuant to N.J.A.C. 13:39-4.21.
- c. The supervising pharmacist must be physically present at the pharmacy practice site or other immunization location and readily and immediately available when the pharmacy technician is administering immunizations.
- d. The pharmacist-in-charge of the pharmacy practice site where vaccines are administered shall ensure that the pharmacy practice site, as well as all authorized

- users at the site, register with the NJIIS, and that all recordkeeping requirements imposed at N.J.A.C. 13:39-4.21 are satisfied.
- e. All vaccines to be administered at a pharmacy practice site or other location under the control and supervision of a pharmacist must be stored and handled consistent with the Board's regulations at N.J.A.C. 13:39-5.11, manufacturer's directions, and the CDC Vaccine Storage and Handling toolkit, found at <a href="https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html">https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html</a>

#### 2. Requirements applicable to COVID-19 vaccinations:

- a. Registered pharmacy technicians may only administer vaccines approved or authorized by the FDA in a manner consistent with the ACIP's COVID-19 vaccine recommendations, pursuant to an order of the supervising pharmacist, an authorized prescriber's patient-specific prescription for a vaccine and related emergency medications, an authorized prescriber's standing order in an immunization program for the vaccine and related emergency medications, or as part of an immunization program sponsored by a government agency or agencies that are not patient specific. Documentation of the pharmacist's order, or a prescriber's prescription or standing order must be maintained at the pharmacy practice site, and if applicable, at the immunization location, as required by N.J.A.C. 13:39-4.21(f).
- b. Prior to authorizing a pharmacy technician to administer a COVID-19 vaccine, the supervising pharmacist shall:
  - Counsel the patient and/or the patient's representative, parent or guardian about contraindications and proper care of the injection site, and provide instructions to contact a primary care practitioner or emergency care facility in the event of any adverse reaction;
  - ii. Provide the patient and/or the patient's representative, parent or guardian with a vaccine information sheet and/or EUA fact sheets published by the CDC;
- iii. Inform the patient and/or the patient's representative, parent or guardian that all vaccines for COVID-19 must be reported to the NJIIS system, and ask for consent to share the information with the patient's primary care practitioner.
- c. Prior to administering an immunization, a pharmacy technician shall:
  - i. For patients under the age of eighteen, inform the patient and/or the patient's parent or guardian, both verbally and in writing, of the importance of a well-child visit with a pediatrician or other licensed primary care practitioner, and refer patients as appropriate.

- ii. Inform the patient and/or the patient's representative, parent or guardian of the potential costs of the vaccine, and that the cost may or may not be covered by the patient's insurance.
- d. The supervising pharmacist shall be responsible to ensure that all COVID-19 vaccines are reported to the NJIIS and/or such other reporting as may be required by the Department of Health and the CDC.
- e. The supervising pharmacist shall document in detail and immediately report all clinically significant adverse events to the appropriate government reporting system within the time required by law.

#### 3. Requirements applicable to childhood vaccinations:

- a. Registered pharmacy technicians may only administer ACIP-recommended immunizations and related emergency medications limited to epinephrine and diphenhydramine, to eligible individuals ages three through seventeen, pursuant to an order of a supervising pharmacist; an authorized prescriber's patient-specific prescription for a vaccine and related emergency medications; an authorized prescriber's standing order in an immunization program for the vaccine and related emergency medications; or as part of an immunization program sponsored by a government agency or agencies that are not patient specific. Documentation of the pharmacist's order, prescriber's prescription or standing order must be maintained at the pharmacy practice site, and if applicable, at the immunization location, as required by N.J.A.C. 13:39-4.21(f).
- b. Prior to authorizing a pharmacy technician to administer a childhood vaccine, the supervising pharmacist shall:
  - i. Ensure that the patient is screened using CDC established criteria for each specific vaccine to be administered, to include determining whether the patient has any contraindications or precautions to vaccination as determined by the ACIP, that can be found at <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html</a>;
  - ii. If the vaccine is to be administered pursuant to a pharmacist's order, the ordering pharmacist shall review the NJIIS or other available vaccination records prior to entering the order, to ensure that the order for the vaccine requested is appropriate for the child and that the vaccine has not been administered by another provider.
- iii. In all instances where vaccine administration is being performed other than pursuant to the pharmacist's order for the vaccine, the supervising pharmacist shall review the NJIIS, both to determine whether the child is enrolled in the

- NJIIS and, if applicable, to ensure that the requested vaccine has not been administered by another provider;
- iv. Obtain a signed informed consent form, from the patient and/or the patient's parent or guardian. The informed consent form shall include a section where the patient and/or the patient's parent or guardian shall be requested to identify the patient's pediatrician or other primary care practitioner (collectively "PCP") and to authorize the provision of copies of the patient's vaccine documentation to the patient's identified PCP. If the parent or guardian has not authorized the pharmacist to provide copies of the patient's vaccine documentation to a pediatrician or primary care practitioner (collectively "PCP"), and the patient is not enrolled in NJIIS, the pharmacy technician shall not administer a vaccine to the patient. Information concerning other vaccination options, to including information identifying nearby Federally Qualified Health Centers, shall be provided to the parents and guardians of any such children.
- v. Counsel the patient and/or the patient's parent or guardian about contraindications and proper care of the injection site, and provide instructions to contact a primary care practitioner or emergency care facility in the event of any adverse reaction.
- vi. Inform the patient and/or the patient's parent or guardian, in writing, in specific and readily understood terms, about the risks and benefits of the vaccine and provide the patient and/or the patient's parent or guardian with a vaccine information sheet and/or fact sheets published by the CDC;
- vii. Provide a copy of all patient-related documentation and a copy of the signed informed consent form to each patient receiving an immunization, and/or to the patient's parent or guardian, and to the patient's PCP, if identified and if authorization has been provided on the informed consent form (see paragraph 3(c)(iii) below).
- c. Prior to administering a childhood vaccine, the pharmacy technician shall:
  - i. Inform the patient and/or the patient's parent or guardian both verbally and in writing, of the importance of a well-child visit with a pediatrician or other licensed primary care provider, and refer patients as appropriate.
  - ii. Inform the patient and/or the patient's parent or guardian of the potential costs of the vaccine, and that the cost may or may not be covered by the patient's insurance;
- d. The supervising pharmacist, if a vaccine is administered by a qualified pharmacy technician, shall ensure that all vaccines administered to children enrolled in the NJIIS, including vaccinations administered to children aged seven and above, are

reported to the NJIIS within thirty days of such administration, or any shorter time period that may hereafter be mandated by amendments to reporting timeframes.

- e. The supervising pharmacist, if a vaccine is administered by a pharmacy technician, shall document in detail and immediately report all clinically significant adverse events to any PCP identified on the informed consent form, and to the primary care practitioner who signed the prescription or standing order, if applicable. The supervising pharmacist shall, within 72 hours, ensure that such events are reported to the appropriate government reporting system.
- 4. The provisions of N.J.S.A. 45:14-63 and -80 are waived insofar as they limit the tasks to be performed by pharmacy technicians, and they limit a pharmacist to the supervision of two technicians for the purposes of administering vaccinations.
- 5. To the extent that they conflict with this Order, the provisions of N.J.A.C. 13:39-4.21 and N.J.A.C. 13:39-4.21A are waived and suspended. Any provisions of this rule that are not inconsistent with this Order remain in full force and effect.

This Order shall take effect immediately and shall remain in effect until the end of the state of emergency or public health emergency declared by the Governor in EO 103, whichever is later, unless expressly revoked or superseded by a subsequent Administrative Order issued by the Director of the Division of Consumer Affairs.

Date: January 5, 2021

Paul R. Rodríguez, Director

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